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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,473	04/24/2000	Robert N. Hamlin	10527-003007	7841

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BOSTON, MA 02110

EXAMINER

DYE, RENA

ART UNIT	PAPER NUMBER
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3627

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/557,473

Applicant(s)

HAMLIN, ROBERT N.

Examiner

Rena L. Dye

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,28,29,35-40,42-45 and 48-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 26,28,29,35-40,42-45 and 48-52 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Introduction

1. The rejections/objections of record as set forth in the last Office action (paper no. 20), not repeated herein, have been withdrawn in view of Applicant's amendments to the present claims.

Claim Rejections - 35 USC § 112

2. Claims 26,28,29,35-40,42-45 and 48-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

With respect to claims 26,28,29,35-40,42-45 and 48-52, given their broadest interpretation, the claims would include a medical catheter balloon comprising a first co-extruded layer made of liquid crystal polymer (LCP) and a second co-extruded layer comprising a second polymer, which is not clearly supported by the original disclosure. In particular claim 26 and 44 now include the limitation "a second layer comprising a polymeric material different from that in the first layer" which constitutes new matter.

Applicant's disclosure clearly supports a multi-layer balloon including a tensile layer as an outer layer and a compatible adhesion or bonding inner layer (page 2, line 20 to page 3, line 13). When using LCP, the LCP polymer is specifically disclosed as a high melt temperature polymer that would only be suitable for use as an outer layer (page 3, lines 14-36).

The claims are broader in scope than that which can be supported by the original disclosure.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 26,28,29,35-40,42-45 and 48-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,270,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '086. The comprising language recited in independent claim 26 is broad enough to include the recited outer tensile layer and inner bonding layer of '086. Furthermore, '086 defines the outer tensile layer as including LCP (column 2, lines 31-42).

5. Claims 26,28,29,35-40,42-45 and 48-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,132,824. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '824. The comprising language recited in

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independent claim 26 is broad enough to include the recited first layer of a biaxially oriented polymer (polyester) and a second layer or a biaxially oriented polymer (polyolefin).

Allowable Subject Matter

6. The Examiner would be willing to allow the following claimed subject matter if terminal disclaimers were filed to overcome the obviousness-type double patenting rejections.

Claim 26:

A medical balloon catheter comprising an inflatably expandable balloon configured to be attached to a catheter, the balloon having a outer tensile layer comprising a liquid crystal polymer (LCP) and a bonding inner layer, wherein the balloon has a radial expansion less than about 10 percent when inflated to seven atmospheres.

Claim 44:

A method of making a medical balloon catheter, the method comprising:
co-extruding a multilayer tubular parison comprising an outer tensile layer comprising a liquid crystal polymer (LCP) and a bonding inner layer; blow molding the parison followed by radially expanding of the parison to form an oriented balloon, wherein the balloon has a radial expansion less than about 10 percent when inflated to seven atmospheres.

Response to Arguments

7. Applicant's arguments filed on August 11, 2003 have been fully considered but they are not persuasive.

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Applicant's specification at page 2, lines 32-36, clearly discloses that the composite (balloon) structure includes a tensile layer combined as an outer layer with a chemically and physically compatible adhesion or bonding inner layer which is fabricated from materials having superior glue bonding or melt bonding characteristics.

Applicant's argument at page 1 of the "REMARKS" states that "The specification expressly illustrates the use of tensile material as an inner bonding layer. Polyvinyl chloride PVC is among a list of examples including LCP that can be used in the tensile layer. The specification describes a balloon having PVC as an inner layer and PET as an outer layer. The balloons inner layer of PVC can be bonded to a catheter body", is not convincing.

It appears that although the present specification supports the use of PVC as a tensile layer material (combined with ABS) or a bonding layer material by itself, it does not clearly support the use of LCP in both the tensile layer and bonding layer. The specification clearly sets forth the use of LCP as a material having high tensile strength. There is no clear disclosure of LCP having adhesion properties suitable for use in bonding layer of the disclosed invention. Therefore, one having ordinary skill in the art would not associate PVC and LCP as functional equivalents in being used as tensile and adhesion layers in the presently claimed invention.

In view of Applicant's amendments to the present claims and arguments of record, Applicant appears to be broadening the disclosed invention in attempting to claim that which he did not have the right to at the time of the filing date.

The Examiner acknowledges Applicant's intention to file the appropriate terminal disclaimers upon an indication that the claims are otherwise allowable.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rena L. Dye whose telephone number is 703-308-4331. The examiner can normally be reached on Monday-Thursday 8:30 AM - 7:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703-308-5183. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.



Rena L. Dye
Primary Examiner
Art Unit 3627

R. Dye
October 7, 2003